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Subject: Environmental Defense comments on Phosphonic Acid, [[bis(2-Hydroxyethyl) Amino] Methyl]- Diethyl Ester (Fyrol 6) (CAS# 2781-11-5)

(Submitted via Internet 6/1/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and william.gentit@akzonobel-chemicals.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Phosphonic Acid, [[bis(2-Hydroxyethyl) Amino] Methyl]- Diethyl Ester (Fyrol 6) (CAS# 2781-11-5).

Akzo Nobel Functional Chemicals LLC, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data and proposed studies for phosphonic acid, [[bis(2-hydroxyethyl) amino] methyl]- diethyl ester, known commercially as Fyrol 6. According to this submission, Fyrol 6 is synthesized in a closed system and transported to customers in 55-gallon drums and tank cars, for use as a flame retardant "primarily" in rigid polyurethane foam. Uses other than the "primary use" are not mentioned.

This very brief test plan indicates that most of the required SIDS elements have been addressed for Fyrol 6, and that appropriate studies have been proposed to address those SIDS elements not currently addressed by available data. The test plan states that Fyrol 6 is covalently bound to the substrate in which it is primarily used and thus would not be released as the parent compound; however, no data characterizing unreacted residual levels in the final product were provided to support this statement.

The test plan also states that Fyrol 6 has low environmental and mammalian toxicity. However, biodegradation studies indicate that, should Fyrol 6 be spilled or released into the environment it would be degraded very slowly. Thus, it would seem appropriate that the test plan should contain additional descriptions of any uses of Fyrol 6 other than the primary use, and address to what extent it is also covalently bound to the substrate in these uses. We would also like to see some description of measures taken to avoid its release into the environment.

References for studies described are not provided in the test plan, but are provided in the robust summaries. References should be included in the test plan as well, but we note that most are internal company documents, and as such would not be available to the public even if they are presented in the test plan.

On review of the robust summaries we note that, with exception of the repeated dose toxicity studies where purity was given as 90.7%, the test substances is said to be of "unstated purity". Each of these same studies is said to have been conducted according to GLP guidelines. We would question if studies of test substances of unknown purity meet GLP guidelines. We also encourage the EPA to question the acceptability of these studies for the submission under the HPV Challenge. We also note that

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studies of chromosomal aberrations conducted in 1978 are said to have been conducted under GLP. It's a minor point, but this date precedes modern GLP standards, which were implemented in 1981.

In summary, this submission briefly addresses each of the required SIDS elements; however, many of the studies described in the robust summaries fail to state the purity of the test substance. Thus, the acceptability of this submission is dependent upon EPA's acceptance of these data. We would recommend that acceptance of this submission be based on determination of the purity of the test substance used in each of the studies.

Thank you for this opportunity to comment.

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